Federal State Budgetary Educational Institution of Higher Education "Privolzhsky Research Medical University" of the Ministry of Health of the Russian Federation
(FSBEI HE "PRMU" of the Ministry of Health of Russia)

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PROGRAM
STATE FINAL ATTESTATION
OF GRADUTES IN SPECIALITY
33.05.01 PHARMACY

Qualification: Pharmacist

Nizhny Novgorod
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1. GENERAL PROVISIONS

The program of state final certification of graduates in the specialty 33.05.01 Pharmacy (qualification: pharmacist) is based on the documents:

1. Federal Law "On Education in the Russian Federation" dated 29.12.2012 No. 273-FL.

2. Order of the Ministry of Education and Science of the Russian Federation dated 29.06.2015 No. 636 (as amended on 28.04.2016) "On approval of the procedure for conducting state final certification for educational programs of higher education - bachelor's programs, specialist programs and master's programs".

3. Order of the Ministry of Education and Science of the Russian Federation dated 11.08.2016 N 1037 (as amended on 13.07.2017) "On approval of the federal state educational standard of higher education in the specialty 33.05.01 Pharmacy (specialty level)".

4. Order of the Ministry of Education and Science of the Russian Federation dated 08.08.2016 N 964 "On amendments to certain orders of the Ministry of Education and Science of the Russian Federation concerning the approval of Federal state educational standards of higher education in the area of training and specialties included in the enlarged groups of areas of training and specialties of higher education related to the field of education "Healthcare and Medical Sciences".

5. Regulations "On the procedure for conducting state final certification for higher education programs - bachelor's degree program, specialist programs in the Federal State Budgetary Educational Institution of Higher Education "PRMU" of the Ministry of Health of Russia", approved by order of the rector dated 01.02.2019 No. 13.

2. PURPOSES AND OBJECTIVES OF THE STATE FINAL ATTESTATION

The goal of the state final attestation is to establish the level of training of a graduate of the Privolzhsky Research Medical University (PRMU) to perform professional tasks and the compliance of his/her training with the requirements of the federal educational standard of higher education.

A graduate in the specialty 33.05.01 Pharmacy (qualification: pharmacist) must solve the following professional tasks in accordance with the types of professional activity:

pharmaceutical activity:

- production and manufacture of medicines;
- sale of medicines;
- ensuring conditions for storage and transportation of medicines;
- participation in procedures related to the circulation of medicines;
- participation in quality control of medicines;
- ensuring information about medicines within the limits established by the current legislation;
- conducting health education work with the population;
- forming the motivation of citizens to maintain health.

medical activities:

- providing first aid in the sales area of a pharmacy organization in case of emergency conditions among visitors before the arrival of the ambulance team;

organizational and managerial activities:

- participation in organizing the production and manufacture of medicines;
- organizing and implementing measures for the storage, transportation, seizure and destruction of medicines;
- participation in organizing and managing the activities of organizations engaged in the circulation of medicines, and (or) their structural divisions;
- participation in organizing measures on labor protection and safety, prevention of occupational diseases, monitoring compliance and ensuring environmental safety;
- maintaining accounting and reporting documentation in a pharmaceutical organization;
- compliance with the basic requirements of information security;

research activities:

- analysis of scientific literature and official statistical reviews,

participation in statistical analysis and public presentation of the obtained results;

- participation in solving individual research and applied scientific problems in the field of circulation of medicines.

A person who has successfully completed the full mastery of the main educational program of the higher education specialty developed by PRMU in accordance with the requirements of the state educational standard of higher education and passed all tests and exams established by the curriculum is admitted to the final certification tests included in the final state attestation.

Subject to successful completion of all established types of final attestation tests included in the final state attestation, the graduate is awarded the appropriate qualification and a state diploma of higher education.

3. REQUIREMENTS FOR GRADUATES IN SPECIALTY 33.05.01 PHARMACY

The results of mastering the BEP are determined by the competencies acquired by the graduate, i.e. his / her ability to apply knowledge, skills, abilities and personal qualities in accordance with the tasks of professional activity.

As a result of mastering the specialist program, the graduate must have developed universal, general professional and professional competencies.

A graduate of the specialist program must have the following

– UC-1. Able to critically analyze problem situations based on a systems approach, develop an action strategy

– UC-2. Able to manage a project at all stages of its life cycle

– UC-3. Able to organize and manage the work of a team, developing a team strategy to achieve the set goal

– UC-4. Able to apply modern communication technologies, including in a foreign language(s), for academic and professional interaction

– UC-5. Able to analyze and take into account the diversity of cultures in the process of intercultural interaction

– UC-6. Able to determine and implement the priorities of his/her own activities and ways to improve them based on self-assessment and education throughout life

– UC-7. Able to maintain the proper level of physical fitness to ensure full social and professional activity

– UC-8. Able to create and maintain safe living conditions, including in emergency situations.

A graduate of the specialist program must have the following general professional competencies (GPC):

– GPC-1. Able to use basic biological, physicochemical, chemical, mathematical methods for the development, research and examination of drugs, the manufacture of drugs

– GPC-2. Able to apply knowledge of morphofunctional features, physiological states and pathological processes in the human body to solve professional problems

– GPC-3. Able to carry out professional activities taking into account specific economic, environmental, social factors within the framework of the system of regulatory and legal regulation of the sphere of circulation of drugs

– GPC-4. Able to carry out professional activities in accordance with the ethical standards and moral principles of pharmaceutical ethics and deontology

– GPC-5. Able to provide first aid on the premises of a pharmaceutical organization in

case of emergency conditions in visitors before the arrival of an ambulance team

– GPC-6. Able to use modern information technologies in solving problems of professional activity, observing the requirements of information security. A graduate of the specialist program must have professional competencies (PC) corresponding to the type (types) of professional activity, which the specialist program is focused on:

– PC-1. Able to manufacture drugs for medical use

– PC-2. Able to solve problems of professional activity in the implementation of dispensing and selling medicines and other goods of the pharmacy range through pharmaceutical and medical organizations

– PC-3. Able to carry out pharmaceutical information and consulting in the dispensing and sale of medicines for medical use and other goods of the pharmacy range

– PC-4. Able to participate in monitoring the quality, effectiveness and safety of medicines and medicinal plant materials

– PC-5. Able to participate in the planning and organization of resource provision of a pharmaceutical organization

– PC-6. Able to organize the supply of medicines and medical products when providing assistance to the population in emergency situations at the stages of medical evacuation

– PC-7. Able to carry out operations related to the technological process in the production of medicines, and their control

– PC-8. Able to solve problems of professional activity within the framework of pharmaceutical activity in the field of circulation of medicines for veterinary use

– PC-9. Able to solve problems of professional activity during transfer of medicines through pharmaceutical and medical organizations

– PC-10. Able to carry out measures to control (supervise) the activities of legal entities and individuals licensed for pharmaceutical activity, to comply with mandatory requirements

– PC-11. Able to take part in measures to ensure the quality of medicines in industrial production

– PC-12. Able to take part in conducting chemical-toxicological and forensic chemical research for the purpose of diagnosing poisoning, drug and alcohol intoxication.

As a result of training in theoretical and practical disciplines of the specialty, the graduate should have the knowledge, skills and abilities that ensure the solution of professional problems.

The graduate should know:

– the structure of the modern healthcare system of the Russian Federation;

– the fundamentals of the legislation of the Russian Federation on the protection of public health and ensuring sanitary and epidemiological well-being in the country;

– the main regulatory and legal documents;
– legal, legislative and administrative procedures and strategy concerning all aspects of pharmaceutical activity;
– the fundamentals of medical deontology and psychology of the relationship between a doctor and a pharmacist, a pharmacist and a consumer of drugs and other pharmaceutical products, when providing first aid and caring for patients and victims in emergency situations;
– the specifics of social insurance and social security, the basics of organizing insurance medicine in the Russian Federation, the healthcare system in the Russian Federation;
– the specifics of a pharmacist's work on concluding contracts with enterprises, institutions, insurance companies in accordance with the procedure established by law;
– principles of organizing pharmaceutical care (outpatient and inpatient) to various groups of the population; – principles of organizing drug provision of outpatient and inpatient patients with drugs and other pharmaceutical products at full cost, as well as citizens entitled to social assistance;
– principles of organizing the procurement of medical property for state and municipal needs;
– the concept of consumer value, consumer properties of drugs and other pharmaceutical products and factors influencing them;
– methods of analyzing the range of drugs and other pharmaceutical products;
– requirements for labeling, packaging and storage of drugs and other pharmaceutical products; – principles of managing a workforce;
– maintaining accounting records by pharmaceutical enterprises of the wholesale and retail links;
– organization of work of mid-level pharmaceutical and auxiliary personnel of pharmaceutical organizations;
– basic principles of state regulation and the process of pricing of pharmaceutical products at all stages of product movement;
– rules for conducting pharmaceutical examination of prescriptions and requirements of medical and other organizations;
– methods of preparing reports for internal and external users of accounting information; – methods of determining the need and demand for various groups of drugs and other pharmaceutical products;
– technology of storing drugs and other pharmaceutical products;
– procedure for dispensing drugs and other pharmaceutical products from a pharmacy to the population, medical and other organizations;
– organization of the manufacture of extemporaneous dosage forms according to prescriptions and requirements of medical and other organizations;
– basic principles of accounting for inventory, funds and settlements;
– principles and rules for settlements with personnel;
– main forms of non-cash payments for goods and services;

– taxation systems for pharmaceutical organizations;
– basics of office work in pharmaceutical organizations;
– techniques for compiling external reports for pharmaceutical organizations (accounting, statistical, tax);
– methods of financial analysis of key performance indicators for pharmaceutical organizations;
– principles of auditing and managing business processes in pharmaceutical organizations;
– principles of developing a business plan for pharmaceutical organizations;
– methods of selecting, placing and recording personnel movement;
– basic principles of preventing population morbidity;
– general patterns of pharmacokinetics and pharmacodynamics of drugs;
– types of drug interactions and types of drug incompatibility;
– features of pharmacotherapy in newborns and the elderly, pregnant women;
– the belonging of medicinal products to certain pharmacological groups, pharmacodynamics and pharmacokinetics of medicinal products, the most important side and toxic effects, the main indications and contraindications for use;
–drug dosing taking into account the nature of the disease, chronobiology and chronopharmacology;
– modern characteristics of toxic chemicals, biological agents, radioactive substances;
– regulatory documentation governing the production and quality of drugs in pharmacies and pharmaceutical enterprises;
– basic requirements for dosage forms and their quality indicators;
– the nomenclature of industrially produced drugs;
– the nomenclature of modern excipients, their properties, purpose;
– technology of dosage forms obtained in pharmaceutical production;
– technology of manufacturing drugs in a pharmacy;
– theoretical foundations of biopharmaceuticals, pharmaceutical factors influencing the therapeutic effect in extemporaneous and industrial production of dosage forms;
– the structure and operating principles of modern laboratory and production equipment;
– the main trends in the development of pharmaceutical technology, new directions in the creation of modern dosage forms and therapeutic systems;
– modern biotechnological methods for obtaining drugs: genetic engineering, protein engineering, enzymology engineering, chromosomal engineering, cell engineering;
– the most important technological processes for processing plant and animal raw materials and producing pharmaceutical products;
–characteristics of the raw material base of medicinal plants;
– general principles of rational procurement of medicinal plant raw materials and measures to protect natural, exploited thickets of medicinal plants;
– classification system of medicinal plant raw materials (chemical, pharmacological,

botanical, morphological);

– nomenclature of medicinal plant materials and medicinal products of plant and animal origin approved for use in medical practice;

– main groups of biologically active compounds of natural origin and their most important physicochemical properties, biosynthesis pathways of the main groups of biologically active substances;

– methods of isolation and purification of the main biologically active substances from medicinal plant materials;

– main methods of qualitative and quantitative determination of biologically active substances in medicinal plant materials, biological standardization of medicinal plant materials;

– requirements for packaging, labeling, transportation and storage of medicinal plant materials in accordance with regulatory documents;

– main ways and forms of using medicinal plant materials in pharmaceutical practice and industrial production;

– general methods for assessing the quality of medicines, the possibility of using each method depending on the method of obtaining medicines, raw materials, structure of medicinal substances, physicochemical processes that may occur during storage and circulation of medicines;

– factors affecting the quality of medicines at all stages of circulation;

– the possibility of preventing the influence of external factors on the quality of medicines;

– chemical methods underlying the qualitative analysis of medicines;

– the main structural fragments of medicinal substances by which inorganic and organic medicinal substances are identified;

– equipment and reagents for chemical analysis of medicines;

– requirements for reagents for testing for purity, authenticity and quantitative determination of medicines;

– equipment and reagents for physicochemical analysis of medicinal substances;

– basic diagram of refractometer, photocolorimeter, spectrophotometer, gas-liquid chromatography, high-performance liquid chromatography;

– structure of regulatory documents governing the quality of medicines, features of the structure of a pharmacopoeial article and a pharmacopoeial article of an enterprise;

– features of the analysis of individual dosage forms;

– concepts of disintegration, dissolution, strength, features of the analysis of soft dosage forms;

– physicochemical constants of drugs, methods for determining melting point, angle of rotation, specific absorption index, boiling point; concept of validation;

– validation characteristics of qualitative and quantitative analysis methods;

– basic patterns of distribution and transformation of toxic substances in the human body (toxicokinetics, toxicodynamics), general characteristics of toxic action;

– classification of narcotic drugs, psychotropic and other toxic substances and their physical and chemical characteristics;
– regulatory and legal documentation governing the procedure for the pharmacy to accept prescriptions and requirements of medical organizations;
– regulatory and legal documentation governing the procedure for the pharmacy to dispense medicines and other pharmaceutical products to the population and medical organizations;
– regulatory, reference and scientific literature for solving professional problems.
The graduate must be able to:
– observe ethical and deontological principles of relationships in professional activities with colleagues, medical workers and the population;
– apply in practice the methods and techniques of marketing analysis in the system of drug provision to the population, medical and other organizations;
– draw up organizational and administrative documentation in accordance with state standards;
– organize certification of workplaces, conduct safety and health training for pharmaceutical workers and auxiliary personnel, measures to prevent environmental violations and violations of labor protection and safety;
– select accounting methods and prepare documents on accounting policies;
– carry out pharmaceutical examination of prescriptions and requirements of medical and other organizations;
– sell drugs and other pharmaceutical products;
– determine the cost of finished drugs and extemporaneous dosage forms;
– carry out prescription accounting;
– conduct subject-quantitative accounting of drugs and other pharmaceutical products in pharmaceutical organizations;
– provide the population entitled to state social assistance;
– document the conduct of laboratory work;
– determine the demand and need for various groups of pharmaceutical products;
– draw up documentation of the established form on the manufacture, storage, registration and dispensing of drugs and other pharmaceutical products from pharmacy organizations;
– analyze the state of inventories and determine sources of their financing;
– select a supplier, conclude supply contracts and prepare documentation on the claim form;
– place orders for the supply of goods;
– set prices for pharmaceutical products, including in-house manufacturing;
– ensure the necessary storage conditions for medicines and other pharmaceutical products during transportation and in distribution network facilities;
– use merchandising principles and methods of stimulating sales of pharmaceutical products
– keep track of cash flows;
– conduct an inventory of inventory items, cash;

– keep track of business transactions;
– analyze the financial and economic condition of the pharmacy and develop measures to improve the efficiency of pharmaceutical organizations;
– forecast economic performance of pharmaceutical organizations and their structural divisions;
– provide information support for the pharmaceutical business;
– manage the personnel of pharmaceutical organizations, implement an effective personnel policy using motivational attitudes;
– manage socio-psychological processes, prevent conflict situations in the team and in interaction with consumers of pharmaceutical goods and services;
– inform and consult the population, medical workers and pharmaceutical workers about drugs, their analogues and synonyms;
– inform and consult medical and pharmaceutical workers and the population about the main characteristics of drugs, belonging to a certain pharmacotherapeutic group, indications and contraindications for use, the possibility of replacing one drug with another and rational administration and storage rules;
– inform and consult the population about the preventive properties of pharmaceutical products;
– determine groups of drugs for the treatment of a particular disease and select the most effective and safe drugs;
– predict and evaluate adverse drug reactions, know the procedure for registering them;
– determine the optimal dosing regimen adequate to the therapeutic objectives;
– perform their professional duties when working as part of special health care units, units and institutions of the civil defense medical service and the all-Russian disaster medicine service, organize the work of a pharmacy and provide drug provision in emergency situations;
– inform doctors, pharmaceutical workers and the population about the main characteristics of drugs, their belonging to a certain pharmacotherapeutic group, indications and contraindications for use, the possibility of replacing one drug with another and rational use, and storage rules;
– prepare documentation of the established form on the manufacture, storage, registration and dispensing of medicines from the pharmacy;
– observe the ethical and deontological principles of relationships in professional activities with colleagues, medical workers and the population;
– comply with labor protection and safety regulations;
– identify and prevent pharmaceutical incompatibility;
– calculate the total mass (or volume) of drugs, the amount of drugs and excipients, individual single doses (in powders, pills, suppositories), draw up written control passports;
– dose solid, viscous and liquid drugs by mass using pharmacy scales;
– dose liquid drugs by volume using pharmacy burettes and pipettes, as well as drops;

– select the optimal technology option and manufacture dosage forms;
– select packaging material and label depending on the type of dosage form, route of administration and physicochemical properties of drugs and excipients;
– evaluate the quality of drugs based on technological indicators: at the stages of manufacture, finished product and dispensing;
– evaluate the technical characteristics of pharmaceutical equipment and machines;
– organize the receipt of finished dosage forms;
– draw up a material balance for individual components of the technological process;
– calculate the amount of raw materials and extractant for the production of extraction preparations;
– select excipients when developing dosage forms taking into account the influence of biopharmaceutical factors;
– calculate the amount of drugs and excipients for production;
– manufacture industrially produced drugs;
– ensure compliance with industrial hygiene, environmental protection, labor protection, and safety regulations; take into account the influence of biotechnological factors on the efficiency of the technological process and maintain optimal conditions for the biosynthesis of the target product;
– determine medicinal plant materials in whole and crushed form using appropriate identifiers;
– recognize impurities of foreign plants during raw material analysis;
– determine reserves and possible volumes of medicinal plant materials;
– determine the main numerical indicators (moisture, ash, extractive substances) using methods in accordance with current requirements;
– accept medicinal plant materials, take samples necessary for their analysis in accordance with current requirements;
– plan the analysis of drugs in accordance with their form according to regulatory documents and assess their quality based on the results obtained;
– prepare reagents, standard, titrated and test solutions, carry out their control;
– determine general quality indicators of medicinal substances: solubility, melting point, density, acidity and alkalinity, transparency, color, ash, loss in weight on drying;
– interpret the results of UV and IR spectrometry to confirm the identity of medicinal substances;
– use various types of chromatography in the analysis of medicinal substances and interpret its results;
– establish the quantitative content of medicinal substances in the substance and dosage forms by titrimetric methods;
– establish the quantitative content of medicinal substances in the substance and dosage forms by physicochemical methods;
– conduct tests for the purity of medicinal substances and establish impurity limits by chemical and physicochemical methods;

– use methods of financial and economic analysis, analysis of the main performance indicators of pharmacies;
– conduct analysis of the property and liabilities of the pharmacy;
– assess the degree of risk of entrepreneurial activity;
– segment the pharmaceutical market and select target segments;
– conduct stage-by-stage quality control in the production and manufacture of medicines;
– use the rules for calculating the optimal technological parameters of fermentation and their adjustment;
– use methods of personnel management of a pharmaceutical enterprise;
– ensure compliance with labor protection and safety regulations and labor legislation

The graduate must possess:

– methods, means and techniques for organizing work in the main links of the pharmaceutical market distribution system;
– organization of pharmaceutical activities;
– skills in accepting prescriptions and requirements of medical and other organizations;
– skills in carrying out pharmaceutical examination of prescriptions and requirements of medical and other organizations, dispensing drugs and other pharmaceutical products according to prescriptions and requirements of medical organizations;
– skills in dispensing drugs and other pharmaceutical products to the population, medical and other organizations;
– regulatory, reference and scientific literature for solving professional problems;
– methods of personnel management of pharmaceutical organizations, compliance with labor protection and safety regulations and labor legislation, ensuring safe working conditions for personnel;
– skills in accounting of inventory items: cash and settlements;
– skills in preparing reports for internal and external users of accounting information;
– methods of studying demand, forming an assortment and forecasting the need for drugs and other pharmaceutical products;
– methods of determining the information needs of consumers of medicinal products and other pharmaceutical goods, providing information and consulting services, using modern resources for information support of the pharmaceutical business;
– methods of forming prices for medicinal products and other pharmaceutical goods;
– skills in maintaining administrative records;
– skills in observing the principles of ethics and deontology in communicating with medical and pharmaceutical workers, consumers of pharmaceutical goods and services;

– technology for creating the necessary sanitary regime of a pharmacy organization;
– skills in dosing solid and liquid medicinal substances by weight using pharmacy scales, liquid preparations by volume;
– skills in packaging and registration of medicinal forms for dispensing;
– techniques for manufacturing all types of medicinal forms in a pharmacy;
– skills in drawing up a written control passport for the manufacture of extemporaneous medicinal forms;
– skills in drafting process sections of industrial regulations for the production of finished dosage forms, including process and equipment schemes for the production of finished dosage forms;
– techniques for carrying out all stages of immobilization and use of immobilized biological objects;
– skills in identifying medicinal plants by external characteristics in living and herbarized forms;
– techniques for preparing micropreparations of various morphological groups of medicinal plant materials;
– techniques for carrying out qualitative and microchemical reactions to the main biologically active substances contained in medicinal plants and raw materials (polysaccharides, essential oils, vitamins, cardiac glycosides, saponins, anthracene derivatives, coumarins, flavonoids, tannins, alkaloids);
– skills in interpreting the results of drug analysis to assess their quality;
– standard operating procedures for determining the order and executing documents for the declaration of conformity of the finished product with the requirements of regulatory documents;
– skills in using chemical, biological, instrumental analytic methods for identifying and determining toxic, narcotic substances and their metabolites;
– techniques for using physicochemical, titrimetric, gravimetric and chromatographic methods of analyzing medicinal plant raw materials;
– methods for conducting in-pharmacy quality control of medicines

4. STAGES AND PROCEDURE OF THE STATE FINAL ATTESTATION

The state examination in the specialty 33.05.01 Pharmacy (qualification: pharmacist) is conducted in stages and includes the following mandatory certification tests:

- checking the level of theoretical preparedness by means of test control;
- checking the level of mastery of practical skills;
- final interview.

The program of the state final certification is communicated to students no later than six months before the start of the state final certification.

The state examination allows to identify theoretical and practical preparation for solving professional problems based on state requirements for the minimum content and level of training of a graduate in this specialty.

The requirements for the mandatory minimum content and training of a graduate are determined by the program of the state examination in the specialty, developed on the basis of the federal state educational standard of higher professional education and the qualification characteristics of a graduate in the specialty 33.05.01 Pharmacy.

The dates of the stages of the state examination in the specialty are determined by the schedule, which is drawn up in accordance with the curriculum and approved by the rector.

Students must be provided with the program of the state examination, have the opportunity to familiarize themselves with the structure and samples of tasks for all stages of the exam.

To conduct the state examination, a fund of assessment tools is used, developed by the employees of the graduating departments:

- Department of Management and Economics of Pharmacy and Pharmaceutical Technology,
- Department of Pharmaceutical Chemistry and Pharmacognosy.

The stages of the state examination in the specialty are held at open meetings of the state attestation commission with the participation of at least 2/3 of their composition.

Stage I - attestation testing.

Verification of the professional training of the graduate, i.e. level of his competence in using the theoretical base. The test material covers the content of the humanities, mathematics, natural sciences, medical and biological and professional disciplines. The composition of the test tasks of the final exam is subject to annual updating in a single bank of certification tasks.

Stage II - practical training.

The practical professional training of the graduate is assessed. It is carried out on the relevant bases that form the basis of the pre-graduate training system in the specialty Pharmacy 33.05.01. The practical training is tested by demonstrating practical skills, using dummies, specialized pharmaceutical equipment, tools, recipes, etc. The duration of the stage should enable the graduate to consistently perform the entire necessary volume of skills and abilities for professional activity.

Stage III - final interview

Checking the professional training of the graduate, i.e. the level of his competence in

using the theoretical base to solve professional situations.

The interview is conducted on the basis of solving situational problems of a generalized nature. In this case, the assessment is subject to the degree of the graduate's ability to develop and implement optimal solutions to such situations based on the integration of the content of the disciplines included in the certification test.

Solving professional problems is carried out during the final interview on complex situational problems. The program, form and conditions of the state examination in the specialty are communicated to the students.

The first student is given up to 60 minutes to prepare for the answer, the rest of the students answer in turn. No more than 30 minutes are allocated for the student's answer on the ticket and questions from the commission members.

The results of the first two stages of the state exam are assessed on a two-point system as "passed" and "failed" and are the basis for admission to the final interview on complex situational problems and the defense of the final qualification work.

The results of the final stage of the state exam (final interview) are assessed on a four-point system: "excellent", "good", "satisfactory", "unsatisfactory". Based on the results of the three stages, a final grade is given for the state exam.

The results of each stage of the state exam are announced to the graduate on the same day after the minutes of the meeting of the state attestation commission have been drawn up and approved in the established manner.

The decision on admitting a graduate who received a “fail” grade at the stage of practical training or attestation testing to the next stage of the state exam is made by the state attestation commission.

Persons who have completed the mastery of the main educational program and have not confirmed the compliance of their training with the requirements of the state educational standard of higher professional education when passing the state exam are assigned a repeat result upon reinstatement to the University new certification tests.

A diploma with honors is issued to a graduate based on the grades entered in the diploma supplement, including grades for disciplines, coursework, practical training and the final interview. Based on the results of the final interview, a graduate must have only "excellent" grades. At the same time, "excellent" grades, including grades for the final interview, must be at least 75%, the remaining grades - "good". Credits are not included in the percentage calculation.

5. RECOMMENDATIONS FOR STUDENTS ON PREPARING FOR THE STATE EXAM

Independent preparation for the state exam in general professional and special disciplines includes both repetition at a higher level of the blocks and sections of the state educational program obtained in the process of professional training, submitted for the exam, and deepening, consolidation and self-testing of acquired and existing knowledge.

To master the list of practical skills, students need to undergo training at the Training Pharmacy.

To prepare for computer testing, students should use the test tasks presented on the distance education portal in training mode. To conduct rehearsal testing in online mode, a bank of test tasks for graduates in all specialties "Tests for the state final certification" is open on the distance education portal. Three tests are provided, once a week. Upon completion of testing, the graduate is advised to review the protocol to familiarize himself with the test results. To prepare for the final interview, the student is offered to use the list of questions presented in the Program and situational tasks developed on the basis of the studied material.

5. STATE EXAM PROGRAM

6.1. During **the 1st stage (attestation testing)**, a bank of tasks in test form is used.

6.2. During **the 2nd stage (practical training),** the student must demonstrate practical skills in four basic disciplines: pharmacy management and economics, pharmaceutical chemistry, pharmacognosy and pharmaceutical technology.

6.3. **The 3rd stage (final interview)** is conducted using tickets containing situational tasks, which include questions on the disciplines of UEF, FT, PH, FG.

6.4. To prepare for the state exam, the use of examination questions is provided:

6.4.1. Pharmacy management and economics

1. Pharmaceutical complex. Features of the pharmaceutical market. State regulation of the pharmaceutical market. Three-tier system of legislation on circulation of medicines.

2. Basic concepts and provisions, improper advertising, categories of goods, advertising of which is not allowed. Requirements for advertising of different categories of goods in the pharmacy range, features of advertising of OTC and Rx drugs.

3. Organization of relations between a pharmacist and a consumer of drugs. Protection of consumer rights: basic concepts and provisions. Rules for the sale of certain types of goods: basic concepts and provisions.

4. Protection of public health in the Russian Federation. Basic principles of health protection, responsibilities of citizens in the field of health protection. Responsibilities of pharmaceutical workers; restrictions imposed in the exercise of

their professional activities.

5. The concept of the market, subjects and objects of the market, types of markets. Supply, the law of supply. Factors influencing supply (price and non-price determinants).

6. Demand, the law of demand, types of demand, features of demand formation for drugs. Factors influencing demand (price and non-price determinants).

7. Market equilibrium and its main parameters. Excess supply and unsatisfied demand. The law of supply and demand. The influence of price and non-price factors.

8. Elasticity of demand for price and income, elasticity of supply for income, cross elasticity. Types of elasticity, elasticity factors, types of goods.

9. Theory of consumer behavior. Methods of studying consumer behavior, brief description. The main stages of making a purchase decision.

10. The main directions of product and assortment policy. Product, structure of the product range. Classification of goods sold by pharmacy organizations.

11. Analysis of the life cycle of goods in the pharmacy range. Characteristics of the stages of the product life cycle. Types of life cycle curves. Analysis of the "business portfolio" of the organization. Analysis of marketing indicators of the pharmacy range.

12. Optimization of the range of drugs taking into account the speed of implementation. Analysis of economic indicators of the pharmacy range (ABC, XYZ, ABC/XYZ analysis). Analysis of pharmacoeconomic indicators of the range (VEN analysis). Approaches to the classification of the product range of pharmaceutical organizations by areas of its analysis.

13. Logistics, objects of logistics management, basic concepts of logistics management. Brief characteristics of the main types of logistics.

14. Purchasing logistics. Selection of a supplier. Transport logistics, the main stages of transportation management. Transportation alternatives and criteria for selecting logistics intermediaries.

15. Inventory logistics. Classification of stocks, basic inventory management systems. Calculation of the optimal order size and time interval between orders.

16. Warehousing logistics. Pharmaceutical warehouse: tasks, functions. Options for organizational structure. The procedure for dispensing goods from a pharmacy warehouse.

17. Sales logistics. Organization of product distribution in the pharmaceutical market, levels of logistics channels. Wholesale pharmaceutical organizations: tasks, functions.

18. Pharmaceutical marketing: purpose and objectives, forms, principles, functions. Marketing complex. Factors influencing consumption of pharmaceutical products.

19. Marketing methods for determining the need for drugs. Studying the demand for goods in the pharmacy range, types of demand. The system of marketing research of

drugs.
20. Basic marketing strategies: analysis of the company's marketing environment, SWOT and STEP analysis, portfolio strategies, market segmentation.
21. Retail link in the system of promotion of pharmacy goods. Nomenclature of pharmacy organizations, tasks and functions. Forms of ownership and organizational and legal forms of pharmacy organizations.
22. Nomenclature of full-time positions of pharmacy workers. Options for the organizational structure of a pharmacy. The composition of the premises of pharmacy organizations depending on the functions performed.
23. Legislation of the Russian Federation in the field of licensing of pharmaceutical activities. The procedure for opening and licensing a pharmacy organization.
24. General principles of organizing the storage of drugs in pharmacy organizations.
25. Features of storing individual groups of goods in a pharmacy warehouse. Receipt, storage and accounting of goods in a pharmacy warehouse, inventory management.
26. Requirements for the design of the sales area of a pharmacy organization and the design of display cases. Basic principles of merchandising.
27. Organization of the work of pharmacy organizations for the sale of goods and services. Over-the-counter dispensing of drugs. Organization of workplaces of specialists in the sales area.
28. Organization of the work of a pharmacy for accepting prescriptions and dispensing drugs: pharmaceutical examination, registration. Registration of primary documentation at the workplace of a pharmacist-technologist.
29. Organization of the manufacture of dosage forms, semi-finished products, in-pharmacy preparations, manufacture of concentrates and semi-finished products. Taxation of prescriptions and the procedure for their registration.
30. In-pharmacy quality control of dosage forms, drugs dispensed from pharmacy organizations. Equipment of a workplace for quality control of drugs, basic documentation.
31. State regulation of the circulation of controlled groups of drugs. Item-quantitative accounting in a pharmacy.
32. Features of obtaining, storing and accounting for narcotic drugs, psychotropic substances and their precursors.
33. Organization and maintenance of the item-quantity accounting (IQA) in a pharmacy organization.
34. Organization of drug provision for inpatients (in the absence of a pharmacy in the structure of a health care institution; in the presence of a pharmacy in the structure of a health care institution).
35. Planning and forecasting. Key economic indicators of pharmacy organizations. Strategic and operational planning, main methods and stages, types of plans.
36. Turnover, classification, analysis of turnover. Factors influencing the volume of sales of goods and services. Planning and forecasting the volume and structure of turnover: stages, methods, sources of information.
37. Commodity stocks: characteristics, classification, indicators. Factors influencing the size of inventories. Analysis and planning of inventories. Methods for determining the optimal size of inventories. Planning the receipt of goods.

38. Costs: characteristics, classification. Factors Affecting the Costs of a Pharmacy Organization. Methods of Managing the Costs of a Pharmacy Organization: Cost Analysis, Main Areas of Cost Saving, Cost Planning.
39. Price, Functions, and Types of Prices. Main Stages of Implementing the Pricing Strategy of a Pharmacy Organization. Pricing Methods. Formation of a Pricing Policy for Medicines in a Pharmacy Organization. Features of the Pricing Policy of Pharmacy Chains.
40. The System of State Regulation of Prices for Medicines. Methodology for Calculating Trade Markups. Methodology for Forming Prices for Pharmaceutical Drugs.
41. Revenue Management. Types and Sources of Revenue Generation. Factors Affecting Sales Income. Income Analysis and Planning. Development of Measures to Ensure the Fulfillment of the Income Plan.
42. Profit Management. Types and Sources of Profit Generation. Profit Functions. Profit Analysis and Planning. Ways to Maximize Profit. Determining the Break-Even Point of an Organization.
43. The Role of Business Accounting in the Activities of a Pharmacy Organization. Types of Accounting, Accounting Measures. Accounting, tasks and functions.
44. Accounting, tasks and functions. Subject and objects of accounting. Classification of property of a pharmacy organization.
45. Method and main elements of the accounting method. Accounting policy of a pharmacy organization.
46. Fixed assets and intangible assets of a pharmacy organization: classification, accounting of receipt and disposal, document flow, valuation, revaluation, depreciation. Inventory of fixed assets and intangible assets.
47. Accounting of raw materials and materials: classification, accounting of receipt and disposal, valuation, document flow.
48. Accounting of receipt and sale of goods, formation of the selling price. Accounting of finished goods. Document flow.
49. Accounting of cash and settlement transactions. Rules for implementing cash transactions. Receipt, storage and issue of cash from the cash desk. Cash book and cashier's reporting. Cash inventory.
50. Settlements using cash register equipment. Purchase and registration of cash register equipment. Cash payments using cash register equipment. Payments using payment cards.
51. Basic systems of remuneration, types wages. Accounting of working hours. Accrual and payment of wages. Document flow.
52. Deductions from wages. Payment of wages. "Wage" taxes.
53. Vacation: provision, payment. Accrual and payment of benefits. Settlements with accountable persons. Other settlements with personnel.
54. Inventory of inventory items. Objectives, deadlines, procedure. Documentation.
55. Inventory of cash and settlements in a pharmacy organization. Objectives, deadlines, procedure. Documentation.
56. The final financial result of a pharmacy organization. Classification of income and expenses for accounting purposes. Reporting of a pharmacy organization. Types and

deadlines for reporting. Audit and forms of control over the financial and economic activities of an organization.
57. Tax accounting. Tax policy of a pharmaceutical organization. General taxation regime, special tax regimes. Taxpayer liability.
58. Theoretical foundations of management. The main stages of management evolution: the main schools of management. Approaches to management.
59. Management mechanisms and management technologies. Models and methods in pharmaceutical management.
60. Organizational design of a pharmaceutical organization. The architectonics of a pharmaceutical organization, the internal and external environment of the organization.
61. Main types of organizational structures. Regulation of the organization's activities.
62. Decision-making in the process of managing a pharmaceutical organization: basic concepts, classification of decisions. The process of making management decisions.
63. Delegation of authority, power, responsibility. Basic principles of delegation.
64. The workforce of a pharmaceutical organization: general concepts and characteristics. Functions, principles and directions of HR management in a pharmaceutical organization. Nomenclature of pharmaceutical specialties.
65. Regulation of labor relations within a pharmaceutical organization (employment contract, job description, work book).
66. Organization of safe working conditions (labor protection). Personnel adaptation.
67. Personnel motivation: basic concepts, management tasks in implementing the motivation function. Motivational theories.
68. Motivation as a dynamic process, stages. Managing the motivational field of a pharmaceutical organization.
69. Styles of workforce management.
70. Conflict management in a pharmaceutical organization.
71. Organization of office work in a pharmaceutical organization. Types of documents, their functions, details.
72. Fundamentals of entrepreneurial activity. Market, its features, types. Features of entrepreneurial activity. Entrepreneurial entities. Entrepreneurial risks.
73. Business planning. Structure of a business plan, algorithm for its development. Procedure for organizing and registering a pharmaceutical organization.
74. The procedure for licensing pharmaceutical activities and activities related to the circulation of ND, PS and their precursors.
75. State supervision and control of the activities of a pharmaceutical organization. The procedure for conducting control.
76. Documentary sources of scientific pharmaceutical information.
77. Marketing methods for studying the information needs of pharmaceutical market entities
78. Communication policy in pharmacy: methodological approaches to advertising and promotion of drugs and other pharmacy products.
79. The system for protecting the rights of consumers of pharmaceutical goods and services.

6.4.2. Pharmaceutical chemistry

1) State principles and provisions governing the quality of medicines. Legislation of the Russian Federation on the circulation of medicines and other pharmaceutical products.

2) Regulatory documentation and standardization of medicines. GF, FS, FSP. International and regional collections of unified requirements and methods for testing medicines, the European Pharmacopoeia, the WHO International Pharmacopoeia and other regional and national pharmacopeias.

3) Sources and methods for obtaining medicines: isolation from natural raw materials; reproduction of physiologically active natural substances; synthesis based on metabolites and antimetabolites. Computer modeling and forecasting the biological activity of new compounds.

4) Ensuring the quality of medicines. Organization of quality control of medicines. Quality control of medicines in production (industrial enterprises and pharmacies).

5) Features of in-pharmacy control of medicines. Tasks of a pharmacist-analyst. Express method for analyzing an extemporaneous formulation and in-pharmacy preparations.

6) Features of pharmaceutical analysis in connection with the intended purpose of drugs. Complex nature of quality assessment depending on the pharmacological action, method of obtaining the dosage form, dosage and method of administration.

7) Possible causes of impurities, their nature and character. Methods for establishing the content of impurities based on the degree of sensitivity of chemical reactions. The effect of impurities on the qualitative and quantitative composition of the drug and the possibility of changing its pharmacological activity.

8) Methods of quantitative analysis of drugs. Prerequisites for choosing a method that allows assessing the content of a drug by functional groups characterizing its properties. Features of quantitative analysis of pharmaceutical substances and drugs.

9) Validation of analytical methods. Validation characteristics of the main types of methods. Establishing the specificity of qualitative and quantitative analysis methods, determining foreign impurities. Linearity. Precision. Accuracy and correctness of analytical methods. Limit of detection and quantification. Robustness.

10) Quality control of medicines during storage. Study of the shelf life of medicines.

11) Inorganic compounds.

12) - Potassium iodides. Sodium fluoride.

13) - Purified water, water for injection. Hydrogen peroxide solution. Sodium thiosulfate, sodium metabisulfite. Sodium bicarbonate, lithium carbonate.

14) - Calcium chloride, calcium sulfate. Magnesium oxide, magnesium sulfate. Aluminum hydroxide, aluminum phosphate. Sodium tetraborate.

15) - Basic bismuth nitrate. Zinc oxide, zinc sulfate. Silver nitrate, collargol (colloidal silver), protargol (silver proteinate). Copper sulfate.

16) – Iron (II) sulfate. Maltofer, cisplatin.

17) Organic compounds

18) - Halogenated hydrocarbons. Halothane (fluorothane).

19) - Alcohols, aldehydes and ethers. Ethyl alcohol, glycerol (glycerin),

polyethyleneglycol, nitroglycerin, diethyl ether (medical ether and ether for anesthesia), formaldehyde solution.
20) - Carbohydrates (mono- and polysaccharides) and their derivatives. Glucose, lactose, glucosamine, chondroitin sulfate, starch, hydroxyethyl starch, hyaluronic acid. Carboxymethylcellulose.
21) - Carboxylic acids and their derivatives. Sodium acetate, calcium lactate, calcium gluconate, sodium citrate, sodium valproate, meldonium (mildronate), sorbic acid.
22) Uronic acid derivatives. Alginic acid.
23) Lactones of unsaturated polyoxycarboxylic acids. Ascorbic acid.
24) Amino acids and their derivatives. Glutamic acid, aminocaproic acid, gamma-aminobutyric acid (aminalone), methionine, cysteine, acetylcysteine, aspartame.
25) Polyaminopolycarboxylic acid derivatives. Tetacin calcium (calcium sodium edetate).
26) Piracetam, phenotropil as analogs of gamma-aminobutyric acid lactam.
27) Proline derivatives: captopril, enalapril, lisinopril.
28) Monocyclic terpenes: menthol, validol, terpin hydrate.
29) Bicyclic terpenes: camphor, sulfocamphoric acid and its novocaine salt (sulfocamphocaine).
30) Diterpenes: retinols and their derivatives (vitamins of group A) as medicinal and prophylactic agents.
31) Statins. Lovastatin, simvastatin.
32) Cyclopentanoperhydrophenanthrene derivatives.
33) - Calciferols (D vitamins) as products of sterol conversion. Mechanism of formation of vitamins ergocalciferol (D2) and cholecalciferol (D3).
34) Cardenolides (cardiac glycosides). Structure and classification. Standardization. Biological and physicochemical methods for quantitative assessment of cardiac glycoside activity. Stability. Digitalis glycosides: digitoxin, digoxin. Corticosteroids. Deoxycortone acetate (deoxycorticosterone acetate). Cortisone acetate, dexamethasone. Gestagens and their synthetic analogues. Progesterone, norethisterone, medroxyprogesterone acetate. Androgens. Testosterone propionate, methyltestosterone. Anabolic steroids: methandienone (methandrostenolone), nandrolone phenylpropionate (phenobolin), nandrolone decanoate (retabolil). Antiandrogens: cyproterone acetate (androcur). Estrogens. Estrone and estradiol as drugs. Prerequisites for obtaining derivatives: ethinyl estradiol, estradiol esters. Antiestrogens: tamoxifen. Analogues of non-steroidal estrogen structure: hexestrol (sinestrol), diethylstilbestrol.
35) Medicines of the phenol group: phenol, thymol, resorcinol, ethamsylate, guaifenesin.
36) Derivatives of naphthoquinones (vitamins of group K): menadione sodium bisulfite (vicasol).
37) Derivatives of aminophenol. Paracetamol. Neostigmine methylsulfate (proserin).
38) Aromatic acids and their derivatives. Benzoic and salicylic acid and their salts. Ethyl parahydroxybenzoate. Acetylsalicylic acid. Ibuprofen, ketoprofen. Diclofenac sodium.
39) Butyrophenone derivatives. Haloperidol.

40) Aromatic amino acids and their derivatives. Benzocaine, procaine hydrochloride, tetracaine hydrochloride. Trimecaine hydrochloride, lidocaine hydrochloride. Procainamide hydrochloride, metoclopramide hydrochloride. Sodium p-aminosalicylate. Amidotrizoic acid and its sodium and N-methylglucamine salts (Triombrast for injection).
41) Arylalkylamines and their derivatives. Ephedrine hydrochloride. Dopamine (dopamine). Epinephrine (adrenaline) and norepinephrine (noradrenaline), their salts. Isoprenaline hydrochloride, fenoterol, salbutamol, verapamil.
42) Derivatives of hydroxyphenylaliphatic amino acids: levodopa, methyldopa.
43) Derivatives of substituted aryloxypropanolamines (β-blockers): propranolol hydrochloride (anaprilin), atenolol, timolol, bisoprolol, fluoxetine.
44) Amino dibromophenylalkylamines: bromhexine hydrochloride, ambroxol hydrochloride.
45) Iodinated derivatives of aromatic amino acids. Liothyronine (triiodothyronine), levothyroxine (thyroxine). Complex drug - thyroidin.
46) Amides of benzenesulfonic acid and their derivatives. Sulfanilamide (streptocide). Furosemide, hydrochlorothiazide (dichlorothiazide, hypothiazide).
47) Sulfonamides: Sodium sulfacetamide, co-trimoxazole, sulfadimethoxine, sulfalene. Phthalylsulfathiazole (phthalazole), salazopyridazine.
48) Benzenesulfochloramide derivatives: chloramine B, galazon (pantocid).
49) Sulfonic acid amide derivatives as antidiabetic agents. Carbutamide (Bucarban), glipizide (Minidiab), glibenclamide, gliclazide (Predian), gliquidone (Glurenorm).
50) Non-aromatic antidiabetic drugs - biguanides: metformin.
51) Furan and 5-nitrofuran derivatives. Nitrofural, furagin, nifuratel. Amiodarone, griseofulvin.
52) Chromane compounds as medicinal and prophylactic agents (vitamins of group E - tocopherols). Tocopherol acetate.
53) Benzo-gamma-pyrone derivatives: Cromoglycic acid (sodium cromoglycate).
54) Phenylchromane compounds: Rutoside (rutin), quercetin, dihydroquercetin, diosmin.
55) Pyrrole and pyrrolizidine derivatives: Cyanocobalamin, hydroxocobalamin, cobamamide. Platyphylline hydrotartrate, povidone (polyvinylpyrrolidone).
56) Pyrazole derivatives. Phenazone (antipyrine), metamizole sodium (analgin), phenylbutazone (butadion), propyphenazone.
57) Indole derivatives. Indomethacin, arbidol, vinpocetine.
58) Ergoline derivatives (ergot alkaloids and their derivatives): nicergoline.
59) Imidazole and 1,2,4-triazole derivatives. Pilocarpine hydrochloride, bendazole hydrochloride, clonidine hydrochloride, metronidazole, naphazoline nitrate, clotrimazole, omeprazole, afobazole, domperidone, xylometazoline. Fluconazole.
60) Histamine dihydrochloride.
61) Antihistamines: diphenhydramine hydrochloride, chloropyramine, ranitidine, famotidine.
62) Piperidine derivatives: trihexyphenidyl hydrochloride, ketotifen, loratadine, loperamide hydrochloride.

63) Dihydropyridine derivatives: nifedipine, amlopidine, nicardipine.
64) Pyridinecarboxylic acid derivatives: nicotinic acid, nicotinamide, nikethamide, sodium salt of N-nicotinoyl-gamma-aminobutyric acid, betahistine. Isoniazid, phthivazid, prothionamide, ethionamide.
65) Pyridinemethanol derivatives. Pyridoxine hydrochloride, pyridoxal phosphate, ethylmethylhydroxypyridine (emoxipine).
66) Alkaloids, tropane derivatives, and their synthetic analogs. Atropine sulfate, scopolamine hydrochloride, homatropine hydrobromide, tropacin, etc.
67) Quinoline and isoquinoline derivatives. Quinine, quinidine and their salts. Chloroquine phosphate, hydroxychloroquine sulfate. Nitroxoline (5-NOC), chlorquinaldol. Papaverine hydrochloride, drotaverine hydrochloride, Morphine, codeine and their salts. Apomorphine hydrochloride, ethylmorphine hydrochloride, glaucine hydrochloride. Trimeperidine hydrochloride (promedol), tramadol hydrochloride, fentanyl.
68) Fluoroquinolones: lomefloxacin, ofloxacin, ciprofloxacin.
69) Piperazine derivatives - cinnarizine.
70) Pyrimidine derivatives. Phenobarbital, sodium thiopental, benzonal, hexobarbital sodium. Methyluracil, fluorouracil. Tegafur (Ftorafur), zidovudine (azidothymidine), stavudine. Primidone (hexamidine).
71) Hydantoin derivatives. Phenytoin (diphenin).
72) Purine derivatives: caffeine, theophylline, theobromine, sodium caffeine benzoate, aminophylline (euphylline), diprophylline, xanthinol nicotinate, pentoxifylline. Acyclovir (Zovirax), ganciclovir (Cymevene). Inosine (riboxin), allopurinol, mercaptopurine, azathioprine.
73) Pteridine and isoalloxazine derivatives. Folic acid and its analogues. Methotrexate. Riboflavin, riboflavin mononucleotide.
74) Phenothiazine derivatives. Chlorpromazine hydrochloride, levomepromazine, trifluoperazine dihydrochloride. Etacizine, moracizine hydrochloride
75) Benzodiazepine derivatives. Chlordiazepoxide, diazepam, nitrazepam, phenazepam.
76) Dibenzodiazepine derivatives: clozapine (azaleptin).
77) 1,2-Benzothiazine derivatives: piroxicam.
78) 10,11-dihydrodibenzocycloheptene derivatives: amitriptyline.
79) 1,5-Benzothiazepine derivatives: diltiazem. Iminostilbene derivatives: carbamazepine.
80) Pyrimidinothiazole derivatives. B1 vitamins. Thiamine chloride and bromide, phosphotiamin, cocarboxylase, benfotiamine.
81) Beta-lactamides. General characteristics and structure. Relationship between structure and biological action. Benzylpenicillin. Amoxicillin. Cephalexin, cefazolin, cefaclor, cefotaxime, cefoxitim
82) Beta-lactamase inhibitors and combination drugs: sulbactam, clavulanic acid. Amoxiclav
83) Aminoglycoside antibiotics: streptomycin sulfate, kanamycin sulfate, gentamicin sulfate, amikacin.

84) Tetrahydropyrrole derivatives. Lincomycins: lincomycin hydrochloride, clindamycin.
85) Macrolides and azalides: erythromycin, azithromycin.
86) Tetracyclines. Tetracycline hydrochloride.
87) Aromatic nitro derivatives: chloramphenicol and its esters (stearate and succinate). Nimesulide.

6.4.3 Pharmacognosy

1) Basic concepts of pharmacognosy: medicinal plant, medicinal plant material, medicinal plant product, biologically active substances. Nomenclature of medicinal plant material and medicinal products of plant and animal origin. Classification of medicinal plant material (chemical, pharmacological, botanical, morphological).
2) Definition of basic concepts of groups of medicinal plant material: leaves, herbs, flowers, barks, roots, rhizomes, rhizomes with roots, rhizomes and roots, fruits, seeds.
3) The importance of pharmacognosy in the practical activities of a pharmacist.
4) Ways and forms of use and application of medicinal plant material and animal material in medicine.
5) Rational methods of procurement of medicinal plant material. Primary processing, drying, storage. Requirements of regulatory documents for packaging, labeling, transportation and storage of raw materials (whole and crushed). Measures to protect natural, exploited thickets of medicinal plants.
6) Acceptance of medicinal plant materials (whole and crushed). Sampling for analysis of raw materials and analysis in accordance with the current ND.
7) Basic information on the distribution and areas of distribution of medicinal plants. Determination of reserves and volumes of procurement of medicinal plant materials.
8) Structure of the FS for medicinal plant materials. Quality requirements. General and specific articles of the GF for medicinal plant materials.
9) Evaluation of the quality of raw materials. Methods of macroscopic and microscopic analysis of whole and crushed medicinal raw materials. Morphological and anatomical features of medicinal plant materials. Determination of the main numerical indicators (moisture, ash, extractive substances) in accordance with ND.
10) Main groups of biologically active substances of natural origin: physicochemical properties, biosynthesis pathways, methods of isolation and purification.
11) Biological standardization of medicinal plant materials.
12) Requirements for the quality of medicinal plant materials in accordance with the general article of the State Pharmacopoeia.
13) Medicinal plant materials "Leaves". Leaves of belladonna, purple foxglove, large-flowered foxglove, eucalyptus, coltsfoot, henbane, peppermint, bogbean, plantain, orthosiphon, sage, senna, datura, nettle, bearberry, lingonberry, wormwood, lily of the valley.
14) Medicinal plant materials "Herbs". Herbs of adonis vernalis, wormwood, succession, shepherd's purse, celandine, centaury, lily of the valley, horsetail, marsh cudweed, St. John's wort, yarrow, motherwort, oregano, knotweed, peppery knotweed, bird's knotweed, lanceolate thermopsis, thyme, violet.
15) Medicinal plant materials "Barks". Bark of buckthorn, oak, viburnum.

16) Medicinal plant materials "Roots, rhizomes, tubers, bulbs". Marshmallow roots, Manchurian aralia, ginseng, horsetail, rhubarb, dandelion, licorice, aralia, rhizomes of bergenia, calamus, snakeroot, cinquefoil, rhizomes and roots of elecampane, rose rhodiola, medicinal burnet, madder, rhizomes with roots of valerian, bluehead.
17) Plant materials "Flowers". Flowers of marigold, blue cornflower, chamomile, hawthorn, sandy immortelle, black elderberry, tansy, linden, lily of the valley.
18) Medicinal plant materials "Fruits". Fruits of hawthorn, rose hips, dill, fennel, anise, caraway, juniper, blueberry, coriander, rowan, bird cherry, buckthorn, viburnum, alder fruit.
19) Medicinal plant material "Seeds". Pumpkin, flax, and lemongrass seeds.
20) Other groups of medicinal plant materials, according to the State Pharmacopoeia: shoots of marsh wild rosemary, birch and pine buds, chaga, corn silk, kelp thalli.

6.4.4 Pharmaceutical technology

1) Medicines and excipients. Classifications. Effect of excipients on bioavailability, stability, microbiological purity and therapeutic efficacy of a medicinal product.
2) Dosage form. Modern concept of dependence of biological activity of a medicinal product on physicochemical properties of dosage forms.
3) Legislative bases for standardization of manufacture and production of medicinal products. Standardization of quality of medicinal products, composition of medicinal products, manufacturing conditions and production processes.
4) General principles of organization of modern pharmaceutical production in conditions of large, small enterprises and pharmacies.
5) Pharmaceutical factors determining therapeutic efficacy of medicinal products. Biopharmacy. Biological availability. Pharmaceutical tests and devices.
6) Mechanical processes and devices. Grinding. Theoretical bases. Grinding machines. Classification of crushed material. Mixing of solid materials.
7) Hydromechanical processes and devices. Dissolution. Theory and methods.
8) Mixing solutions. Separation of heterogeneous systems: under the action of gravity, in the field of centrifugal forces, under the action of pressure difference.
9) Thermal processes and apparatuses. Heat transfer mechanisms. Heat carriers. Heating, cooling, evaporation. Characteristics of processes and equipment.
10) Mass transfer processes and apparatuses. Fundamentals of mass transfer theory. Extraction in a liquid-solid system. Extraction in a liquid-liquid system. Adsorption and ion exchange. Crystallization. Distillation and rectification as methods for separating liquid mixtures.
11) Drying. Forms of moisture bonding with a material. Drying kinetics. Dryers.
12) Mass transfer through semipermeable membranes. Basic membrane methods: reverse osmosis, ultrafiltration, evaporation through a membrane, dialysis, electrodialysis.
13) Dosing, transportation.
14) Powders. Technology and equipment schemes for obtaining powders in pharmaceutical production. Manufacturing powders according to individual prescriptions in pharmacies. Quality indicators, standardization.

15) Collections. Technology and equipment schemes for production. Quality indicators, standardization.
16) Tablets. Theoretical foundations of tableting. Tablet composition. Technological schemes for production. Types of granulations. Film-coated tablets. Evaluation of tablet quality. Packing and packaging. Modern types of tablets.
17) Dragees, granules. Technological schemes for production. Quality assessment. Dosing of granules into hard gelatin capsules, disposable bags, bottles.
18) Medical capsules. Technological schemes for obtaining soft and hard gelatin capsules by different methods. Obtaining and evaluating the quality of gelatin mass. Filling capsules with medicinal substances. Evaluation of capsule quality. Packaging, storage.
19) Microcapsules and microgranules. Objectives of microencapsulation and microgranulation. Methods of production. Quality assessment. Dosage forms based on microcapsules and microgranules.
20) Solvents. Purified water, non-aqueous solvents. Ethanol, alcoholimetry.
21) Medical solutions. Technological schemes of production. Calculation of the working prescription. Dissolution, purification methods. Quality assessment.
22) True solutions of low-molecular compounds. Industrial, serial and small-scale production of solutions. Preparation of solutions according to individual prescriptions. Use of a burette system. Preparation of mixtures.
23) True solutions of high-molecular compounds. Influence of the structure of HMC on the dissolution process. Production technology, quality assessment.
24) Solutions of protected colloids. Production technology, quality assessment.
25) Drops. Technology and standardization. Verification of doses of toxic and potent substances.
26) Syrups. Aromatic waters.
27) Suspensions. Industrial, serial and small-scale production of suspensions. Production of suspensions according to individual prescriptions. Evaluation of suspension quality.
28) Emulsions. Industrial, serial and small-scale production of emulsions. Production of emulsions according to individual prescriptions. Evaluation of emulsion quality.
29) Eye dosage forms. Eye drops, ointments, films. Requirements for eye dosage forms. Regulatory documents. Technological schemes. Equipment. Standardization. Packaging.
30) Dosage forms for parenteral use. Solutions, suspensions and emulsions for parenteral administration. Solvents for
injection solutions. Production of water for injection in industrial and pharmacy conditions. Organization of production. GMP rules, orders, instructions. Ensuring the required cleanliness of premises. Requirements for personnel, special clothing, equipment.
31) Production of ampoules and vials for injection solutions. Glass vials and ampoules. Vials, syringes and dropper tubes made of polymeric materials. Production of injection and infusion solutions in industrial and pharmaceutical conditions. Sterilization. Filtration of injection solutions. Assessment of quality quantities.
32) Extraction medicinal herbal preparations.

33) Preparation of raw materials for extraction. Extractants. Basic principles of extraction of capillary-porous raw materials with cellular structure. Extraction methods.
34) Aqueous extracts: infusions and decoctions. Technology, quality assessment.
35) Tinctures. Technological scheme, standardization of tinctures.
36) Extracts: liquid, thick and dry. Oil extracts. Elixirs.
37) Complex mixtures made using extract concentrates.
38) Maximum purified herbal preparations and herbal preparations of individual substances. Technological schemes. Methods of purification of extracts, separation of the sum of extractive substances. Dosage forms.
39) Preparations from fresh plant materials. Juices, extraction preparations. Technological scheme.
40) Biogenic stimulant preparations.
41) Preparations from animal and plant raw materials. Technological schemes for obtaining preparations of dried glands and tissues, preparations for parenteral administration. Highly effective methods of purification and isolation.
42) Technology of manufacturing dosage forms in extreme conditions.
43) Medicinal preparations and forms for newborns and children under 1 year.
44) Medicinal and cosmetic medicinal products.
45) Dosage forms used in homeopathy.
46) Obtaining medicinal and prophylactic drugs by biosynthesis and biotransformation. Fundamentals of modern biomedical technologies.
47) Ointments. Excipients in the production of ointments: bases, emulsifiers, stabilizers. Technology for obtaining ointments of different types. Equipment used in the production of ointments. Quality indicators, packaging.
48) Rectal and vaginal dosage forms. Suppositories. Excipients in suppository production: bases, emulsifiers, stabilizers, preservatives. Methods for obtaining suppositories: pouring, pressing, rolling. Manufacture of suppositories according to individual prescriptions. Quality indicators. Packaging, storage.
49) Pills.
50) Patches. Excipients, production flow charts, quality assessment. Transdermal therapeutic systems.
51) Aerosols. Design and operating principle of an aerosol can. Propellants. Characteristics of the contents of an aerosol can. Flow chart for the production of drugs in aerosol packaging. Aerosol quality assessment.
52) Inhalations.
53) Medical pencils.
54) Films.
55) Pharmaceutical incompatibilities. Main types. Methods of overcoming.

7. EDUCATIONAL AND METHODOLOGICAL MATERIAL OF THE STATE EXAM

7.1. Attestation testing

Choose one correct answer

7.1.1. Pharmacy management and economics

01. The norms for prescribing narcotic drugs per 1 prescription can be increased for incurable cancer patients:

a) 2 times b) 1.5 times c) 3 times d) 4 times e) 10 times.

Correct answer: a

7.1.2. Pharmaceutical technology

01. Draw a conclusion about the compliance of the definition of the dosage form "Powders" with the definition of the State Pharmacopoeia of the XI edition.

"Powders are a dosage form consisting of one or more substances and possessing the property of dispersion"

a) corresponds

b) it should be added, "a dosed dosage form ..."

c) it should be added, "or several liquid and solid substances ..."

d) it should be added, "possessing the property of flowability and ..."

d) does not correspond

Correct answer: d

02. To obtain purified water, the following methods are used

a) reverse osmosis

b) direct osmotic process c) ultrafiltration

d) filtration e) rectification

Correct answer: a

7.1.3. Pharmaceutical chemistry

03. Separation of a substance in a thin layer of sorbent can be attributed to the following type of chromatography:

a) Distribution b) Precipitation

c) Adsorption d) Ion exchange

Correct answer: c

7.1.4. Pharmacognosy

Cardiac glycosides are the main group of biologically active substances in the raw materials

a) wormwood

b) celandine c) licorice

d) yellow poppy e) restharrow

Correct answer: b

7.2 Practical training

7.2.1 List of practical skills in Pharmacy Management and Economics (the graduate must be able to do)

1) Prepare a package of documents to obtain a license for pharmaceutical

activities for a pharmacy.

2) Prepare a package of documents to reissue a license for pharmaceutical activities for a pharmacy of finished dosage forms.

3) Prepare a package of documents to obtain a license for activities related to the turnover of narcotic drugs (ND) and psychotropic substances (PS) for a pharmacy.

4) Document the receipt of ND and PS in a pharmacy organization.

5) Document the results of the inventory of ND and PS at the end of the month.

6) Document the acceptance of goods by the pharmacy from the supplier in terms of quantity and quality.

7) Prepare a product report for the pharmacy organization for the reporting period (month).

8) Conduct an assessment of the assortment of a certain group of drugs (calculate the width, completeness, depth; determine the amount of demand, the price elasticity coefficient).

9) Document the management decision on employee bonuses.

10) Document the write-off of pharmaceutical products for destruction.

11) Document the write-off of ND and PS for destruction.

12) Document the breakage/defectiveness of drugs.

13) Document the withdrawal of funds from the cash register to pay salaries to employees.

14) Document the withdrawal of funds from the cash register for business needs.

15) Document the withdrawal of funds from the cash register for travel expenses of a pharmacy employee.

16) Prepare a package of documents for an employee sent to advanced training courses.

17) Document the accounting of the working hours of pharmacy employees.

18) Conduct a pharmaceutical examination of the prescription.

19) Conduct control during the dispensing of pharmacy products (PP).

20) Document the sending of cash register equipment for technical repairs.

21) Create a job description for a pharmacist-technologist.

22) Create a job description for a pharmacist-analyst.

23) Create a job description for a pharmacist responsible for the quality of pharmaceutical care in a pharmacy organization.

24) Create a package of accompanying documents for a pharmaceutical product arriving at a pharmacy.

25) Design an information stand for the sales area of a pharmacy organization.

26) Document a response to a complaint from a pharmacy visitor.

27) Document the dispensing of an extemporaneous drug.

28) Document the acceptance of a fixed asset in a pharmaceutical organization.

29) Document the inventory of fixed assets in a pharmaceutical organization.

30) Conduct an inventory in a pharmacy organization in connection with a change in the financially responsible person.

31) Document the acceptance of a pharmaceutical product subject to item-quantity accounting (IQA).

32) Resolve a conflict situation that arose between a pharmacy employee and a visitor.

33) Resolve a conflict situation that arose between pharmacy employees.

34) Develop a motivational program for pharmacy employees.

35) Document the shipment of pharmaceutical products from a warehouse to a pharmacy (without ND and PS).

36) Document the shipment of pharmaceutical products from a warehouse to a pharmacy (with ND and PS).

37) Conduct an ABC and XYZ analysis of the pharmacy's product range.

38) Conduct a SWOT analysis of a pharmaceutical organization.

39) Develop an advertising campaign plan for a newly opened pharmacy.

40) Conduct an analysis of the financial condition of a pharmacy based on the balance sheet data.

41) Develop a cost reduction plan for a pharmaceutical organization.

42) Draw up documents for a cash audit.

43) Prepare a report on the sale of drugs to patients entitled to state social assistance.

44) Calculate the wages for pharmacy employees (under the tariff-free system).

45) Determine the amount of vacation pay for employees of a pharmaceutical organization.

46) Document the commissioning of cash register equipment.

47) Conduct an assessment of the performance of pharmacy personnel.

48) Conduct an assessment of the inventory of the pharmacy organization.

49) Document the hiring of a new employee for a job related to the turnover of ND and PS.

50) Forecast the turnover of the pharmacy for the next quarter.

51) Design a display case for the sales area (drugs, medical devices and other TAA).

52) Create a consultative dialogue (with a patient (visitor to the pharmacy), a medical worker) when providing information on a specific drug.

7.2.2. List of practical skills in Pharmaceutical Chemistry (the graduate must be able to do)

1) Determine the content of volatile substances and water in a medicinal substance and make a conclusion on the quality of the studied medicinal product based on the indicator "Loss in weight on drying".

2) Determine the melting point of the medicinal product and make a conclusion on the quality of the medicinal product based on the indicator "Melting point".

3) Determine the density of the medicinal product and evaluate the quality of the medicinal product based on the density value.

4) Determine the solubility of the medicinal product and make a conclusion on the compliance of the medicinal product with the requirements of regulatory documentation for solubility.

5) Determine the transparency and color of the medicinal product and evaluate

the quality of the analyzed solution in comparison with the standard or solvent.

6) Determine the acidity, alkalinity of the medicinal product and evaluate the results.

7) Determine the pH of the medicinal product and evaluate the results.

8) Determine the authenticity of the medicinal product, make a conclusion on the compliance of the medicinal product with the requirements of regulatory documentation for authenticity.

9) Determine impurities in medicinal products and evaluate the results of determination.

10) Evaluate the quality of medicinal products based on ash content.

11) Conduct a quantitative determination of medicinal products using refractometry.

12) Conduct a quantitative determination of medicinal products using thin-layer chromatography.

13) Conduct a quantitative determination of medicinal products using polarimetry.

14) Conduct a quantitative determination of medicinal products using photocolorimetry and spectrophotometry.

15) Conduct a quantitative determination of medicinal products using high-performance liquid chromatography.

16) Conduct an analysis of medicinal products using infrared spectroscopy.

17) Evaluate the packaging, labeling, and expiration date of the medicinal product (in accordance with the requirements of the Federal Service for Standardization).

18) Draw up a conclusion based on the results of the medicinal product analysis, fill out the analytical passport.

7.2.3. List of practical skills in Pharmacognosy (the graduate should be able to do)

1) Identify medicinal plants in living and herbarized forms by morphological features.

2) Use macroscopic analysis to determine the authenticity of medicinal plant materials.

3) Use microscopic analysis to determine the authenticity of medicinal plant materials.

4) Identify medicinal plant materials in whole form using appropriate identifiers.

5) Determine the composition of the official collection.

6) Recognize impurities of foreign plants during collection, acceptance and analysis of raw materials, as well as determine it in whole, cut form.

7) Conduct qualitative and microchemical reactions for the main biologically active substances contained in medicinal plants and raw materials (polysaccharides, essential oils, vitamins, cardiac glycosides, saponins, anthracene derivatives, coumarins, flavonoids, tannins, alkaloids, etc.).

8) Select appropriate chromatography methods for the analysis of medicinal plant materials.

9) Conduct an analysis using quantitative determination methods provided for by the relevant regulatory documentation (RD), of medicinal plant materials for the content of essential oils, cardiac glycosides, saponins, alkaloids, anthracene derivatives, tannins, flavonoids, coumarins, vitamins, etc.

10) Determine moisture, ash, extractive substances using methods provided for by ND.

11) Accept medicinal plant materials, select samples required for their analysis, in accordance with RD.

12) Conduct statistical processing and formalize the results of the harmacognostic analysis.

7.2.4 List of practical skills in Pharmaceutical Technology (the graduate must be able to do)

1) Provide the necessary storage conditions for a specific (specified) drug.

2) Prepare documentation of the established form on the manufacture, storage, registration and dispensing of the specified drug from the pharmacy.

3) Identify and describe methods for preventing pharmaceutical incompatibility.

4) Calculate the total mass (or volume) of the specified drug, the amount of drug and excipients, a separate single dose (in powders, pills, suppositories).

5) Compile a written control passport for the specified drug.

6) Dose a solid, viscous or liquid drug by mass using pharmacy scales.

7) Dose a liquid drug by volume using pharmacy burettes and pipettes, as well as drops.

8) Select the optimal option for the technology and manufacture of the specified drug.

9) Select packaging material and label the medicinal product depending on the type of dosage form, route of administration and physicochemical properties of medicinal and excipients.

10) Assess the quality of the specified medicinal product based on technological parameters: at the stages of manufacturing, finished product and dispensing. Assess the technical characteristics of the specified pharmaceutical equipment.

11) Obtain the finished dosage form using the appropriate equipment.

12) Make a general material balance and a balance for individual components of the technological process.

13) Calculate the amount of raw materials and extractant for the production of the specified extraction medicinal product.

14) Calculate the amount of medicinal and excipients for the production of the medicinal product.

15) Manufacture the specified medicinal product.

16) Ensure the conditions for aseptic implementation of the technological

process and its compliance with modern requirements for the organization of production and manufacturing.

17) Document the laboratory study.

7.2.5. List of practical skills in providing first medical aid (graduates should be able to do):

1) Provide emergency medical care in palliative situations.

7.3 Final interview

Sample case studies.

Management and economics of pharmacy

The licensing authority sent a committee to conduct a routine inspection of compliance with licensing requirements at the pharmacy of PharmPlus LLC. The inspection revealed that: prescription drugs are stored on display, the pharmacist has an expired specialist certificate, and at the time of the inspection, the temperature regime in the refrigerator where the Grippferon drug was stored (the packaging of the drug states “Store at a temperature of 2^0C to 8^0C”, “Dispensed without a prescription”) was violated (15^0C).

1. What licensing requirements exist for a pharmacy to carry out pharmaceutical activities?

2. Who has the right to engage in pharmaceutical activities?

3. How long can the inspection of licensing requirements continue?

4. What violations are considered gross violations of licensing requirements?

5. Can a decision be made to suspend a license, by whom and for how long?

6. Can this JSC be brought to administrative responsibility (which one)?

7. Can the medicinal product Grippferon be displayed on the display case?

Sample answer.

1. Licensing requirements and conditions for pharmacy organizations are established by RF Government Resolution No. 1081 of 22.12.2011 "On licensing pharmaceutical activities" (clause 5)

According to clause 5. of RF Government Resolution No. 1081 of 22.12.2011 "On licensing pharmaceutical activities", a licensee-pharmacy organization must meet the following licensing requirements to carry out pharmaceutical activities:

a) the availability of premises and equipment owned by it or on another legal basis, necessary for the performance of work that constitutes pharmaceutical activities;

d) compliance by the licensee engaged in retail trade in medicinal products with the rules for dispensing medicinal products, the requirements of Part 6 of Article 55 of the Federal Law "On Circulation of Medicines" and the established maximum amounts of retail markups to the actual selling prices of manufacturers for medicinal products included in the list of vital and essential medicinal products;

g) compliance with the requirements of Article 57 of the Federal Law "On Circulation of Medicines" (prohibition of the sale of counterfeit medicinal products, poor-quality medicinal products, counterfeit medicinal products);

h) compliance by the licensee engaged in the storage of medicinal products for medical use - with the rules for storing medicinal products;

k) the head of the organization has higher pharmaceutical education and at least 3 years of work experience in the specialty, or secondary pharmaceutical education and at least 5 years of work experience in the specialty, a specialist certificate;

l) the licensee has employees who have concluded employment contracts with him and have higher or secondary pharmaceutical education and a specialist certificate;

m) advanced training of specialists with pharmaceutical or medical education at least once every 5 years.

2. Relationships arising as a result of pharmaceutical activities, as well as the rights and obligations of pharmaceutical specialists, are defined and regulated by the Federal Law of the Russian Federation of 21.11.2011 No. 323-FZ "On the Fundamentals of Health Protection of Citizens in the Russian Federation".

In accordance with Art. 2 of this law, the concept of "pharmacist" was introduced. A pharmacist is an individual who has a pharmaceutical education, works in a pharmaceutical organization, whose job responsibilities include wholesale and (or) retail trade in drugs, their manufacture, dispensing, storage and transportation.

In accordance with Art. 69, the right to carry out pharmaceutical activities is granted to persons who have received a pharmaceutical education in the Russian Federation in accordance with federal state educational standards and have a specialist accreditation certificate (specialist certificate).

3. According to the Federal Law of 26.12.2008 N 294-FL "On the Protection of the Rights of Legal Entities and Individual Entrepreneurs in the Implementation of State Control (Supervision) and Municipal Control", any type of inspection may last no more than 20 days.

4. In accordance with paragraph 6 of RF Government Resolution No. 1081 of 22.12.2011 "On Licensing Pharmaceutical Activities", a gross violation of licensing requirements and conditions shall be understood as the licensee's failure to comply with the requirements stipulated by subparagraphs "a" - "z" of paragraph 5 of RF Government Resolution No. 1081 of 22.12.2011 "On Licensing Pharmaceutical Activities" (availability of premises and equipment owned or on other legal grounds; compliance with the rules for dispensing medicinal products, the requirements of Part 6 of Article 55 of the Federal Law "On Circulation of Medicines" and the established maximum retail markups to the actual selling prices of manufacturers for medicinal products included in the list of vital and essential medicinal products; compliance with the requirements of Article 57 of the Federal Law "On Circulation of Medicines"; compliance with the rules for storing medicinal products)

5. Violations of licensing requirements were identified in this pharmacy organization (storage of prescription drugs doctor, on the display case (in accordance with the Federal Law of 13.03.2006 N 38-FZ "On Advertising", advertising of drugs dispensed on doctor's prescription is not allowed, and displaying them on the display case is a type of sales promotion, i.e. advertising); the pharmacist does not have a specialist certificate, including gross violations - violation of the storage conditions of the drug Grippferon)

Suspension of activity (Article 20, Federal Law of 04.05.2011 N 99-FL "On Licensing of Certain Types of Activity") - the imposition of an administrative penalty on the licensee in the form of administrative suspension of activity for gross violation of licensing requirements is carried out in the manner established by the legislation of the Russian Federation.

The license shall be suspended by the licensing authority in the following cases:

• bringing the licensee to administrative responsibility for failure to comply within the prescribed period with an order to eliminate a gross violation of licensing requirements issued by the licensing authority;

• imposition of an administrative penalty on the licensee in the form of administrative suspension of activities for gross violation of licensing.

Information on the suspension (as well as on the renewal) of the license is entered into the register of licenses.

This licensee, Apteka LLC, may have its license suspended in the form of an administrative penalty.

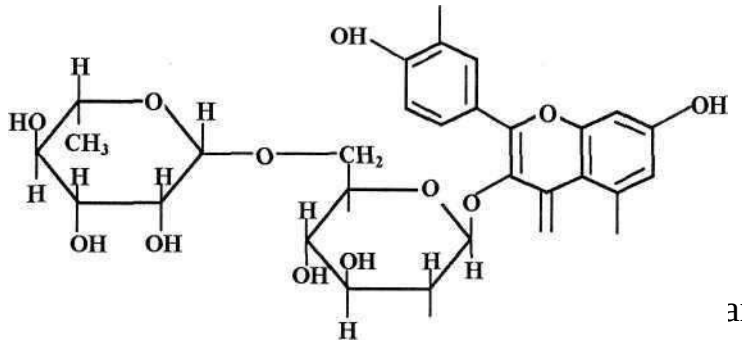
6. In accordance with the "Code of the Russian Federation on Administrative Offenses" dated 30.12.2001 N 195-FZ Article 14.3. Violation of advertising legislation, clause 5. Violation of the requirements established by advertising legislation for advertising of medicines, medical devices and medical services, including treatment methods, as well as dietary supplements - shall entail the imposition of an administrative fine on citizens in the amount of two thousand to two thousand five hundred rubles; on officials - from ten thousand to twenty thousand rubles; on legal entities - from two hundred thousand to five hundred thousand rubles.

In accordance with the "Code of the Russian Federation on Administrative Offenses" dated 30.12.2001 N 195-FL Article 14.1, paragraph 4. Carrying out entrepreneurial activity with a gross violation of the conditions stipulated by a special permit (license) - shall entail the imposition of an administrative fine on persons carrying out entrepreneurial activity without forming a legal entity, in the amount of four thousand to five thousand rubles or administrative suspension of activity for a period of up to ninety days; on officials - from four thousand to five thousand rubles; on legal entities - from forty thousand to fifty thousand rubles or administrative suspension of activity for a period of up to ninety days.

7. Grippferon cannot be put on display, despite being dispensed without a doctor's prescription, since it must be stored in the refrigerator.

Pharmaceutical chemistry

Standardization of raw materials is carried out according to the content of the active substance of the following chemical structure:



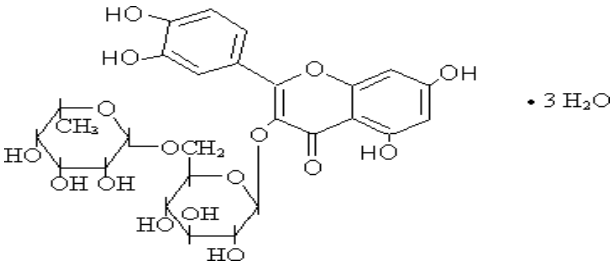
$\times 3H_2O$

онон

1. Present its Russian, Latin and rational name, indicate the pharmacological group, medical use and other natural sources of its production.
2. Justify the physicochemical properties (appearance, solubility in water, spectral characteristics) and the standard indicators determined by these properties.
3. In accordance with the chemical structure and properties of rutin, propose possible reactions for establishing authenticity and methods of quantitative determination.
4. Indicate a specific impurity associated with the production of rutin from medicinal plant materials and propose methods for its detection.

Standard answer

1. Rutinum
Rutinoside



3-rutinoside quercetin (3- rhamnoglycosyl -3,5,7,3',4'-pentaoxyflavone)

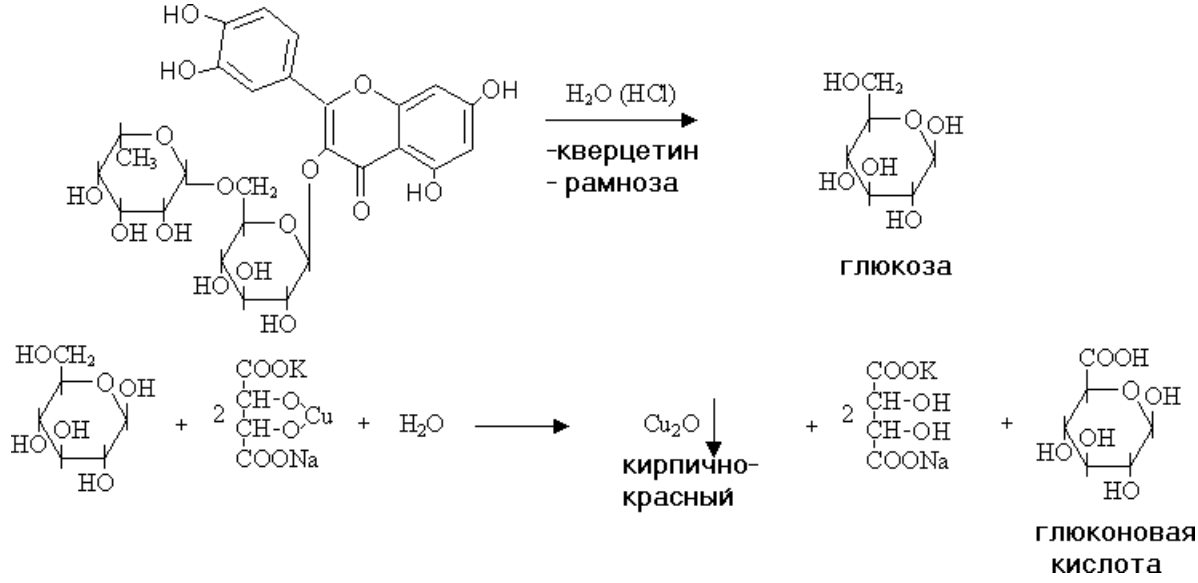
Rutin is a vitamin of group P (flavonoids), which is in the form of a glycoside. The sugar part is a disaccharide consisting of D-glucose and α-rhamnose (rutinose), the aglycone is quercetin. Rutin is found in the leaves of rue (Rutagrateolens), flowers of Japanese pagoda tree (Sophorajaponica), etc. It is used for vitamin P deficiency, as a capillary strengthening agent.

2. *Description*: greenish-yellow finely crystalline powder, odorless and tasteless.

Solubility: practically insoluble in water, chloroform, ether, slightly soluble in 95% alcohol, difficult in boiling alcohol, soluble in caustic alkalis.

Spectral characteristics:

1) IR 4000-700 cm^{-1} (absorption bands of ND) 2) UV spectrum in ethanol λ=258 and 362.5 nm.

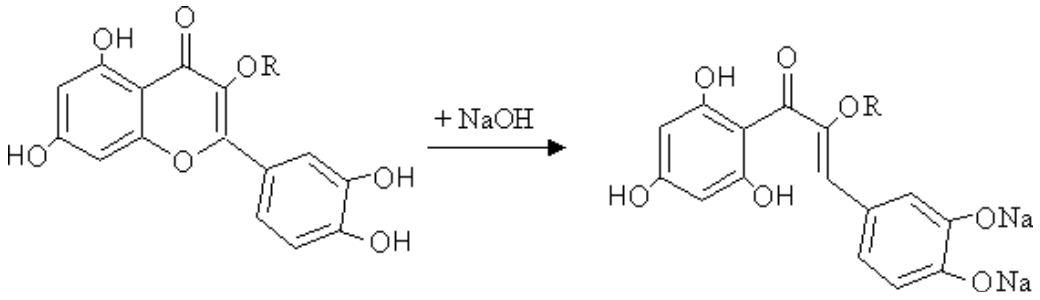


3.

Authenticity:

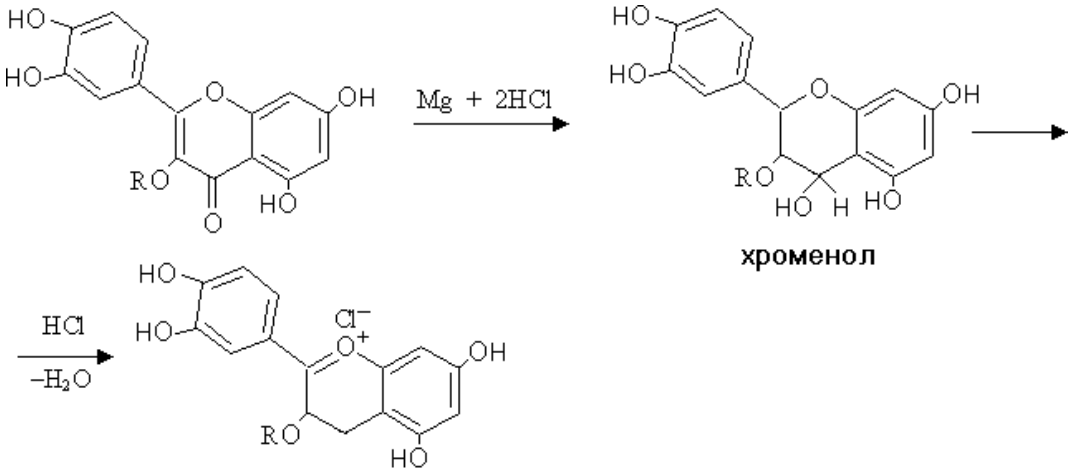
1) First, the preparation is subjected to acid hydrolysis, then glucose is determined with Fehling's reagent.

2) Color reaction of NaOH, formation of chalcone.



Rutoside chalcone, yellow-orange color

3) Cyanine test (reduction of quercetin with hydrogen at the time of isolation).



4) UV spectrum. 0.002% solution of the preparation in absolute alcohol. λmax=259□1 nm 362.5±1 nm.

Quantitative determination: spectrophotometric method.

λмах=375 nm (D_1)

λмах=362,5 nm (D_2)

$E^{1\%}_{1см}$=325,5 if D_1/D_2 = 0,875

$$X = \frac{D_2 1000}{325{,}5a}$$

3. A specific impurity of rutin is quercetin (a product obtained from plant materials, according to the State Pharmacopoeia X should not exceed 5%). The impurity is also determined spectrophotometrically or by paper chromatography (60% acetic acid solution), sprayed with 10% ammonium sulfate solution, at λмах=360 nm in UV light there should be only one quercetin spot.

With UV spectrophotometry at λмах=375 nm (D1), 362.5 nm (D2), if the D1/D2 ratio does not exceed 0.879, then the preparation does not contain quercetin, but if it does, then the quercetin content in percent X is calculated using the formula:

$$X = \frac{D_1 5{,}943 - D_2 5{,}200}{a}$$

Storage: in a tightly sealed container, protected from light.

Pharmacognosy

To obtain the "Bitter Tincture", a batch of raw materials "Marsh trefoil leaves" (whole) was purchased, weighing 2160 kg (net), packed in fabric bales weighing 40 kg (net). Traces of stains are visible on three bales.

1. Carry out acceptance of raw materials: provide the Latin name of the raw materials, producing plants and families; give a definition of the concept "batch of raw materials"; calculate the sample size, average and analytical sample weight; sample collection method for analysis;

2. Specify the anatomical and diagnostic features of marsh trefoil leaves; write the formulas of the main active ingredients, pharmacological group, ways of using raw materials and preparations.

Standard answer

1. **Raw materials:** water trefoil leaves – Folia Menyanthidis

Plant: water trefoil, or bogbean – Menyanthestrifoliata L.; family Bogbean - Menyanthaceae.

A batch is a quantity of raw materials of at least 50 kg of one name, homogeneous in all respects and issued by one document certifying its quality. The document must contain the following data: number and date of issue; name and address of the sender; name of raw materials; batch number; batch weight; year and month of collection or procurement; procurement region (for raw materials from wild plants); raw material quality test results (carried out in the sender's laboratory); name of the regulatory document regulating the quality of raw materials; signature and position of the responsible person.

The weight of the raw material batch is 2160 kg. (net), in a bale of 40 kg. 2160/40 = 54 bales. If the number of places exceeds 50, the sample size is 10% of the number of places, i.e. 5 bales, 3 soaked bales are analyzed separately.

Three spot samples are taken from each selected and opened unit of production: from the top, from the middle and from the bottom at a depth of at least 10 cm from the edge of the package. A spot sample is the amount of medicinal plant material taken from a unit of production in one go by hand or with a probe. The mass of spot samples is not regulated, but they should be approximately the same, if possible.

A combined sample is made up of all the spot samples, which are placed on a commodity board or a table with sides. A combined sample is a set of all the spot samples taken from a batch of medicinal raw materials and thoroughly (but with caution) mixed together. The mass of a combined sample is uncertain and depends on the size of the batch, the characteristics of the raw materials, the size of the spot samples, etc.

All subsequent samples required for various tests are separated using the

quartering method. The essence of the quartering method is that the raw material is leveled on a table or a commodity board in the form of a square in a layer as thin and uniform in thickness as possible and divided diagonally into 4 triangles. Two opposite triangles of raw material are removed, and the two remaining ones are combined together, carefully mixed and leveled again in the form of a square. This procedure is repeated until the raw material remains in the two opposite triangles, the mass of which corresponds to the mass of the average sample required for the analysis of this type of raw material (deviations of ± 10% are possible). In addition to the average sample, a sample weighing 500 g for small species and 1000 g for large types of raw material is isolated from the combined sample (this is combined with the allocation of the average), which is necessary for the precise determination of the degree of infestation with storage pests. This sample is placed in a tightly closing jar, providing it with a label. Samples are also extracted from the combined sample to determine the content of radionuclides (weight 500-1000 g) and microbiological purity (50 g).

The average sample is also packaged, provided with labels on the package and inside it, where, in addition to the contents of the document accompanying the batch, the date of sample collection and the name of the person who collected it should be indicated.

Three analytical samples are extracted from the average sample using the quartering method to determine authenticity, grinding and content of impurities, ash, moisture and active substances. The last two are taken after coarse grinding of the average sample.

An analytical sample is a part of the analyzed average sample, representatively reflecting the quality of the raw materials of the proposed batch.

The error in weighing analytical samples varies from 0.01 g (for a sample weight of up to 50 g) to 5 g (for a sample weight of more than 1000 g). The analytical sample for determining moisture is separated from the average sample first and immediately packaged hermetically.

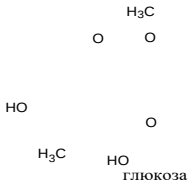
After the external inspection, a sample of undamaged packages taken from different locations is taken to check the quality compliance with the ND requirements. The quality of medicinal plant raw materials from damaged units of packages is checked separately from undamaged ones, opening each unit of packaging.

The selected samples in packaged form, glued with a label indicating the name of the medicinal plant raw material, lot (batch) number, its weight, date of sampling, and the name of the sampler, are sent for analysis to the KAL.

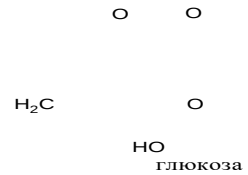
2. Microscopy: when examining the surface of the leaf, polygonal cells of the upper epidermis with straight walls are visible, and cells of the lower epidermis - with slightly convoluted walls. On both sides of the leaf, mainly on the lower one, there are submerged stomata surrounded by 4-7 epidermal cells (anomocytic type). Radial folding of the cuticle is noticeable around the stomata. On the underside of the leaf

under the epidermis is an aerenchyma with large air cavities.

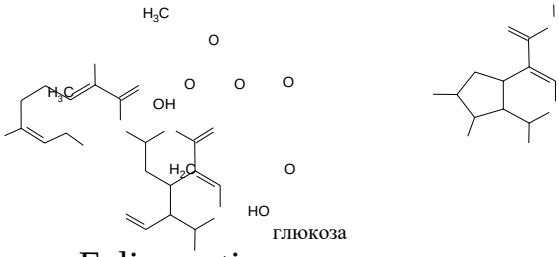
Application. Prescribed, like all bitters, to improve digestion. In addition, it is recommended for diseases of the liver and bile ducts. They produce a thick extract, used to prepare a complex bitter tincture; it is part of the collections - appetizing, choleretic and sedative.



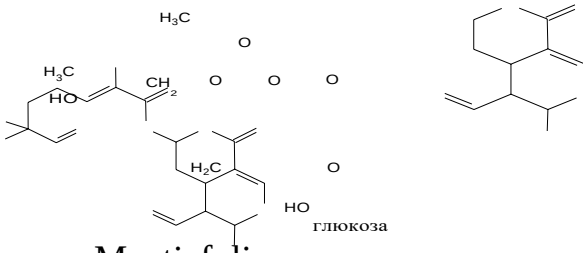
Loganin



Sverozid



Foliamentin



Mentiafolin

Pharmaceutical technology

Task №1. A prescription for the preparation of an extemporaneous вosage form (DF) (ointment) was received by the pharmacy.

Task: determine the sequence of melting the base components according to the prescription:

Take: Peach oil 15.0 Yellow wax 15.0

Anhydrous lanolin 10.0

Answer standard: when determining the sequence of melting the base components, proceed from the melting point of the latter. To avoid overheating, first melt the refractory bases, and then the rest in order of decreasing melting point. The melting point of yellow wax

63-650C, anhydrous lanolin 36-42°C, peach oil is a viscous liquid. The type of lanolin is not indicated in the prescription; therefore, aqueous lanolin is implied.

Task № 2. A pharmaceutical company received 100 liters of belladonna tincture with an alcohol content of 37%, for which 3.20 liters of 40% alcohol were spent. 50 liters of 14.8% alcohol were recovered from the spent raw materials.

Task:

1) draw up a material balance for absolute alcohol;

2) find the output, expenditure and expenditure coefficient.

Answer standard:

1) Absolute alcohol consumed: 40%

X- 120----------= 48 l;

100%

Absolute alcohol obtained in the finished product: 37%

X= 100 ------- =

37 l;100 %

Absolute alcohol recovered:

14,8

X = 50 --------7,4 л;
100
Material balance for absolute alcohol:
48 = 37+7,4+3,6 (material losses)
2) Output:
44,4 (37+7,4)
η| = ---------- ---- x 100=
92,5%;48
Spending:
3,6
ε = x 100 = 7,5%;
48
Expense ratio:48
Красх. =---------- = 1,081
44,4

8. RECOMMENDED REFERENCES FOR PREPARATION FOR THE STATE EXAM

8.1. Main literature

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8.2 Additional literature

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2. Davani, B. Pharmaceutical analysis for small molecules / ed. B. Davani. – [S. I.]: Wiley, 2017. – XXV, 229 p. – ISBN 978-1-119-12111-4. Link to bibliographic description: https://nbk.pimunn.net/MegaPro/UserEntry?Action=Link_FindDoc&id=213240&idb=0
3. Hugo, W. B. Pharmaceutical microbiology / W. B. Hugo; Hugo, W. B. – 4-th ed. – Oxford: Blackwell Scientific Publications, 1991. – 511 p. – ISBN 0-632-01909-3. Link to bibliographic description: https://nbk.pimunn.net/MegaPro/UserEntry?Action=Link_FindDoc&id=29864&i

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4. Nemire, R. E. Pharmacy clerkship manual: a survival manual for students / R. E. Nemire, K. L. Kier; Nemire Ruth E.; Kier Karen L. – McGraw-Hill, 2002. – 524 с.: мяг. – ISBN 0-07-136195-2. Link to bibliographic description: https://nbk.pimunn.net/MegaPro/UserEntry?Action=Link_FindDoc&id=23433&idb=0
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8. The International Pharmacopoeia Fourth Edition – WHO Pharmacopoeia Library, 2011.
9. The Japanese Pharmacopoeia Sixteenth Edition – Tokyo, The Committee on Japanese Pharmacopoeia, 2011, 2326 p.
10. The United States Pharmacopeia (USP 32) and the 27-th edition of the National Formulary (NF 27). – Washington, D.C.: The United States Pharmacopeial Convention, 2009. – 815 p.
11. Clark, M.A., R.Finkel, J.A.Rey, K.Whalen Pharmacology / M.A.Clark et al.–5th ed.–Philadelphia: Wolters Kluwer : Lippincott Williams & Wilkins, 2012.–612 p.: ил.–(Lippincott's Illustrated Reviews).–ISBN 9781451143201.Link to bibliographic description:https://nbk.pimunn.net/MegaPro/UserEntry?Action=Link_FindDoc&id=118958&idb=0

8.3. Software and Internet resources:

1) Electronic library system "Student Consultant" (http://www.studmedlib.ru) 6. Information retrieval database "Medline" (http://www.ncbi.nlm.nin.gov/pubmed)

2) Union catalog "Corbis" (Tver and partners) (http://corbis.tverlib.ru)

3) Scientific electronic library eLIBRARY.RU (http://elibrary.ru)

4) University library online (http://www.biblioclub.ru)

5) Ministry of Health and Social Development [Electronic resource]. Healthcare. - Document Bank / - Access mode: free //http://www.minzdravsoc.ru/

6) Official website of the Federal Service for Consumer Rights Protection and Human Welfare [Electronic resource]. /– Access mode: free // http://www.rospotrebnadzor.ru/

7) Official website of the Central Research Institute of Health Organization and

Information [Electronic resource]. /– Access mode: free // http://www.mednet.ru /

8) Encyclopedia of Russian legislation: the "Garant" system [Electronic resource] http://www.garant.ru/

9) Federal State Statistics Service [Electronic resource] – Access mode: free.- // http://www.gks.ru/

10) http://www.pmda.go.jp/english/pharmacopoeia/online.html

11) http://www.pharmacopoeia.co.uk/2012/.

12) http://www.who.int/medicines/publications/pharmacopoeia/overview/en/index. html.

13) http://www.stoptb.org/gdf

14) http://www.who.int/druginformation

15) http://www.pharmateca.ru/

16) http://www.medlit.ru/

17) http://www.mediasphera.aha.ru/antibiot/antb-mn.htm

18) http://www.springerlink.com/(uacpktayyszhcw45qm22gv55)/app/home/journal.asp?referrer=parent&backto=linkingpublicationresults,1:100413,1

19) http://jac.oxfordjournals.org/archive/

20) http://jpet.aspetjournals.org/

21) http://intl.pharmrev.org/

22) http://www.pharmaexpert.ru/PASSOnline/

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24) http://www.pharmacopoeia.co.uk/2012/.

25) http://www.stoptb.org/gdf

26) http://www.who.int/druginformation

27) http://www.pharmateca.ru/

28) http://www.medlit.ru/

29) http://www.mediasphera.aha.ru/antibiot/antb-mn.htm

30) http://www.springerlink.com/(uacpktayyszhcw45qm22gv55)/app/home/journal.asp?referrer=parent&backto=linkingpublicationresults,1:100413,1

31) http://jac.oxfordjournals.org/archive/

32) http://jpet.aspetjournals.org/

33) http://intl.pharmrev.org/

9. CRITERIA AND SCALES FOR ASSESSING THE RESULTS OF THE STATE EXAM

The results of the final stage of attestation tests are determined by the grades "excellent", "good", "satisfactory", "unsatisfactory" in accordance with the current Regulation on the bank of assessment tools in the Federal State Budgetary Educational Institution of Higher Education "PRMU" of the Ministry of Health of Russia.

Criteria and scales for assessing the State Final Exam

Mark	Criteria
«**Excellent**»	- The student demonstrates a high level of competence, developed systematic knowledge of the program material, educational and periodical literature, reveals basic concepts and analyzes them based on the positions of various authors, sees interdisciplinary connections. Presents the material professionally, competently, consistently, clearly, formulates reasoned conclusions. - The student demonstrates a high level of skills, successfully and systematically applies skills in the disciplines included in the final state exam in the specialty. Demonstrates the formation of competencies that should be formed as a result of mastering the EP. - The student knows the legislative, regulatory and practical framework within the framework of the requirements for the specialty. - The student answers questions from commission members briefly, reasonably, confidently, to the point.
«Good»	The student demonstrates a sufficient level of competence, generally successful, but containing some gaps in knowledge of the lecture material, educational and methodological literature. Confidently and professionally, clearly, distinctly and understandably states

	the state and essence of the question. The answer is constructed logically using informative and illustrative material, but allows some errors when answering. - The student knows the regulatory and legislative framework, but allows minor errors when answering. - The student demonstrates a sufficient level of professional skills, applies skills quite successfully, is fluent in concepts, methods of assessing decision-making. Has an idea of interdisciplinary connections, combines knowledge obtained in the study of various disciplines, can analyze practical situations, but allows some errors. Demonstrates the formation of competencies that should be formed as a result of mastering the BEP. - The questions asked by the members of the examination committee do not cause significant difficulties.
«Satisfactory»	- The student demonstrates sufficient but incomplete knowledge of the educational and lecture material, but the answer lacks the proper connection between analysis, argumentation and conclusions. - The student answers questions posed by the commission members uncertainly, makes mistakes. Has difficulty answering questions posed by the commission, demonstrates insufficiently deep knowledge. - The student has generally successful but not systematic skills, professional abilities, uses illustrative material, but feels insecure when analyzing interdisciplinary connections. The answer does not always contain logic, insufficiently compelling arguments are used. - The student demonstrates generally successful, but with some gaps, formation of competencies that should be formed as a result of mastering the educational program.

«Unsatisfactory»	- The student demonstrates weak fragmentary knowledge (or lack thereof) of lecture material, educational literature, legislation and practice of its application, a low level of competence, an uncertain presentation of the issue. - The student demonstrates a weak level (or lack thereof) of professional skills, fragmentary application of skills (or lack thereof), has difficulty analyzing practical situations. The student cannot provide examples from real practice. - The student presents the material uncertainly and logically inconsistently. The student answers questions posed by the commission members incorrectly or finds it difficult to answer. - The student demonstrates fragmentary or lack of formation of competencies that students should master as a result of mastering the BEP (according to the list of competencies);

10. Change Sheet

Date of the modification	Date and № of the protocol meeting of the Academic Council of the Faculty of Pharmacy	Contents of the change	Signature